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ROCKVILLE, MARYLAND 20852

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. 76N-0210]

RECOMMENDATIONS CONCERNING MAMMOGRAPHY

INVITATION TO SUBMIT DATA, INFORMATION, AND VIEWS

The Food and Drug Administration (FDA) is inviting the submission of data, information, and views on voluntary radiation safety recommendations to minimize unnecessary radiation exposure associated with mammographic examinations. Comments and data should be submitted by (insert date 90 days after date of publication in the FEDERAL REGISTER) to: Office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

The Food and Drug Administration, through the Bureau of Radiological Health and under authority of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.), conducts and supports research, training, and operational activities to minimize unnecessary exposure of the public to electronic product radiation. In carrying out the purposes of the act, the Commissioner of Food and Drugs is authorized to make such recommendations relating to the control of electronic product radiation as he considers appropriate (42 U.S.C. 263d). In this capacity, the Commissioner is considering the development of recommendations to health practitioners and public

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health officials concerning minimization of unnecessary radiation exposure in the conduct of mammographic examinations.

These recommendations would be among several that will be proposed by the Commissioner concerning the hazards and control of electronic product radiation or radiation from other sources. Some of these recommendations may be established in areas or activities inappropriate for mandatory control and thus would be voluntary. They will be developed in cooperation with national scientific and technical authorities and representatives of professional, public, and private groups that have an interest and knowledge in the field. The recommendations would therefore represent a consensus of expert opinion upon which individual practitioners and allied health personnel can rely. These recommendations, which will provide guidance on techniques for reducing unnecessary exposure to electronic products or other sources of radiation, would be implemented through educational programs and cooperative activities with professional organizations and State health agencies. This notice is being issued pursuant to FDA policy of early public participation in the development of radiation protection recommendations by the agency.

Mammography is currently a widely used and accepted diagnostic examination for breast cancer detection. Practitioners employ several mammographic techniques. The range of radiation exposures

associated with proper use of these techniques has been reported to be from less than 1 to over 10 roentgens per view at the surface of the breast, with 2 or 3 views of each breast comprising a typical examination. This variability in exposure is due to a variety of factors, some of which relate to the equipment and technique used and others which relate to the specific diagnostic information of interest. A large segment of the adult female population is likely to undergo a number of mammographic examinations and thus may be subject to a significant exposure to ionizing radiation.

The medical community and public health officials are currently developing methods to minimize the radiation exposure associated with mammography, while still retaining the desired diagnostic information. The Food and Drug Administration has encouraged the implementation of facility-based quality assurance programs in all diagnostic x-ray facilities, including mammography facilities. The goal of such programs is to assure that the facility will produce consistently high quality radiographs at minimum cost and minimum patient exposure.

An advanced notice of the intent to develop quality assurance recommendations was published in the FEDERAL REGISTER of May 7, 1976 (41 FR 18863). Other FDA activities, such as the publication

of quality assurance procedure manuals, the development of equipment catalogs, etc., will provide guidance to diagnostic x-ray facilities as an aid to implementation of individual quality assurance programs. These facility-based programs are expected to minimize unnecessary radiation exposure during all diagnostic x-ray examinations, including mammographic examinations.

Because of the extra potential for high exposure in mammographic examinations, the Commissioner proposes to pursue two additional concurrent projects to minimize unnecessary radiation exposure in this area:

1. The Bureau of Radiological Health has begun pilot tests of a state-based quality assurance program in mammography. The state-based program is designed to identify mammography facilities requiring special attention. In conjunction with one State and one local health department, cooperating clinical facilities are mailed thermoluminescent dosimeters to be exposed at those mammographic technique factors that are used in the craniocaudal view of the "average" breast. In addition to the dosimetry, data are also collected on the type of image receptor and processing, and on the number and age of women being examined. Facilities at which the exposure appears to be high for the image receptor used are visited by trained persons from the appropriate radiation control agency; these persons try to make recommendations to improve one or more aspects of the technique. The goal of the improved technique is to

reduce exposure while retaining or improving diagnostic capability. The information obtained by these pilot studies will be used to make recommendations for state-based mammography quality assurance monitoring and followup procedures, which will be available to all radiation control agencies nationwide. This information is also expected to be of value in implementing the facility-based diagnostic x-ray quality assurance programs.

2. The Bureau of Radiological Health proposes to compile a report that will contain information on technique-equipment combinations presently being used or promoted for use. Currently, a variety of x-ray tubes, technique factors, and image receptors are employed in mammographic examinations. No consensus exists among investigators in the field on the optimal equipment or technique. It appears that the choice depends upon the experience and preference of the practitioner and upon what features he deems most important to visualize. For example, xeroradiography is claimed to be superior in visualizing ductal patterns, whereas diffuse masses may be more easily detected using film as the image receptor. This report would reference data on factors such as the following: x-ray tube target material, type and thickness of x-ray filter, peak kilovoltage, source-to-skin distance, image receptor, imaging qualities, and expected range of exposure to the patient. Such a report could then serve as a guide to the selection of the technique-equipment combination appropriate for minimizing patient dose while obtaining

the desired information. The data used in compiling this report would then be used in conjunction with opinions from the medical community in developing radiation safety recommendations for equipment used in mammography.

Interested persons are invited to participate in developing the proposed recommendations by submitting written data, information, and views on the subject. Comments are particularly desired on the two items described above, namely, the state-based mammography quality assurance program and the mammography technique information report. All such submissions should be identified with the docket number in the heading of this notice and be filed with the Hearing Clerk, Food and Drug Administration. Comments received on or before (insert date 90 days after date of publication in the FEDERAL REGISTER) will be considered by the Commissioner in formulating the recommendations. All recommendations and technical reports that result from this study will be published and made available to all interested parties by means of a notice of availability published in the FEDERAL REGISTER.

Persons or organizations who wish to receive copies of draft recommendations, reports, and any related documents distributed for review during development of the mammography technique information report should write to the Food and Drug Administration, Bureau of Radiological Health, (HFX-440), 5600 Fishers Lane, Rockville, MD 20852.

Dated: June 4 1976.

JUN 4 1976

William F. Randolph

William F. Randolph
Acting Associate Commissioner
for Compliance

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Mary Evans